IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF RHODE ISLAND

DENISE LOY, a resident citizen of the State of Florida, MELISSA CHRESTMAN, a resident citizen of the State of Tennessee, MARY ALEXANDER, a resident citizen of the State of North Carolina, Individually and on Behalf of all Others Similarly Situated,

Plaintiffs,

vs.

WARNER CHILCOTT PUBLIC LIMITED COMPANY, WARNER CHILCOTT COMPANY, LLC, WARNER CHILCOTT HOLDINGS COMPANY III, LTD, WARNER CHILCOTT CORPORATION, WARNER CHILCOTT (US), LLC, WARNER CHILCOTT SALES (US), LLC, WARNER CHILCOTT LABORATORIES IRELAND LIMITED, WARNER CHILCOTT COMPANY, INC., ACTAVIS, INC., WATSON PHARMACEUTICALS, INC., WATSON LABORATORIES, INC., LUPIN LTD., and LUPIN PHARMACEUTICALS INC.

Defendants.

CLASS ACTION COMPLAINT

JURY TRIAL DEMANDED

Civil Action No.

CA 13- 695S

COMPLAINT AND JURY DEMAND

Plaintiffs DENISE LOY, MELISSA CHRESTMAN and MARY ALEXANDER (collectively "Plaintiffs") on behalf of themselves and all others similarly situated, file this Class Action Complaint ("Complaint") against Defendants Warner Chilcott Public Limited Company, Warner Chilcott Company, LLC, Warner Chilcott Holdings Company III, Ltd, Warner Chilcott Corporation, Warner Chilcott (US), LLC, Warner Chilcott Sales (US), LLC, Warner Chilcott

Laboratories Ireland, Limited, and Warner Chilcott Company, Inc., (collectively, "Warner Chilcott"), Actavis, Inc., f/k/a Watson Pharmaceuticals, Inc. and Watson Laboratories, Inc. (collectively, "Watson"), Lupin Ltd. and Lupin Inc. (collectively "Lupin") (Watson and Lupin are collectively referred to as "Generic Defendants," and Warner Chilcott and the Generic Defendants are collectively referred to as the "Defendants"), based upon personal knowledge as to facts pertaining to it, and upon information and belief as to all other matters, and allege as follows:

NATURE OF THE ACTION

1. This is an antitrust class action seeking treble damages arising from Defendants' unlawful and anti-competitive scheme to exclude generics from the market for oral contraceptives comprised of 24 norethindrone acetate/ethinyl estradiol tablets (containing 1mg of norethindrone acetate and 20 mcg ethinyl estradiol) and four ferrous fumarate tablets (placebo), which Warner Chilcott sells under the brand name Loestrin 24 Fe ("Loestrin 24"). Defendants' market-allocation scheme injured Plaintiffs and the Class of end-payor purchasers (as defined below), by preventing generic competition in the market. Defendants accomplished this anti-competitive scheme by unlawfully interfering and circumventing the generic drug regulatory process, delaying the introduction of generic alternatives to the market, and various other anticompetitive measures. Defendants' conduct constitutes an agreement to unreasonably restrain trade in violation of Section 1 of the Sherman Act and various state antitrust and consumer protection laws, and is unjust enrichment in violation of common law.

2. Warner Chilcott initially began selling Loestrin-based oral contraceptives in 1973 and over the past 40 years has continued to obtain new patents based solely on minor variations of those original ingredients. Defendants then encourage physicians to write prescriptions using the latest iteration of Loestrin. Because these patents involve only minor variations of the same product, Warner Chilcott's formulation patents are subject to challenge by generic manufacturers as invalid and unenforceable.

3. On April 15, 2005, Warner Chilcott sought FDA approval to market what became known as Loestrin 24. In connection with its application to the FDA, Warner Chilcott listed U.S. Patent No. 5,552,394 ("the '394 Patent") as covering Loestrin 24 or a method of using Loestrin 24. The active ingredients in Loestrin 24, the hormones norethindrone acetate and ethinyl estradiol, are not protected by any patent. Norethindrone and ethinyl estradiol have served as the active ingredients in oral contraceptives dating back to at least the 1970s.

4. Because the '394 Patent claims only a narrow method of using active ingredients that have been employed for decades as oral contraceptives, generic manufacturers were eager to apply for FDA approval to market generic versions of Loestrin 24 before the expiration of the '394 Patent. Generic manufacturers believed they could obtain a court ruling that the '394 Patent was invalid and unenforceable. Defendants Watson and Lupin sought to do just this and filed challenges to the '394 patent with the intent to distribute generic versions of Loestrin 24.

5. To prevent generic competition from entering the market, Warner Chilcott sued generic manufacturers Watson and Lupin and asserted the generics infringe the '394 Patent. Warner Chilcott filed these patent lawsuits without regard to whether they had legal merit. Warner Chilcott's intent in filing these "sham" patent lawsuits was not to prevail or litigate them to completion. These suits were used solely as a means to delay the onset of generic competition. Under the Hatch-Waxman Act (discussed in detail below), the mere filing of these lawsuits prevented the FDA from approving the generic drug for 30 months, regardless of the merits of the lawsuit. To take advantage of the automatic 30-month delay, Warner Chilcott only needed to file the patent infringement lawsuits, it did not have to prevail in them.

6. Due to the weak nature of the '394 Patent, Warner Chilcott knew it would almost certainly lose the patent cases if litigated to completion. Therefore, as the 30-month stay against the first potential generic competitor – Defendant Watson – was nearing expiration, Warner Chilcott entered into an unlawful and anti-competitive "pay-to-delay" or "reverse payment" agreement with Watson, wherein Watson withdrew its challenge to the '394 patent and agreed to delay entry of its generic alternative into the market until January 2014 – just six months before

the '394 Patent expires. This unlawful agreement to delay generic competition allowed Warner Chilcott and Watson to share in the monopoly profits Warner Chilcott earned from sales of Loestrin 24.

7. Warner Chilcott repeated this scheme with the second potential generic competitor, Defendant Lupin. Again, knowing that it would almost certainly lose the patent case against Lupin if litigated to conclusion, Warner Chilcott entered into an unlawful and anti-competitive "pay-to-delay" or "reverse payment" agreement with Defendant Lupin. In exchange for substantial payments from Warner Chilcott, Lupin agreed to withdraw its challenge to the patent and delay entry until July 2014 (the very end of the patent term.) The Chilcott-Watson and Chilcott-Lupin "pay-to-delay" or "reverse payment" agreements further perpetuated Warner Chilcott's monopoly in the market for oral contraceptives comprised of 24 norethindrone acetate/ethinyl estradiol tablets and four ferrous fumarate tablets and ensured end-users would continue to pay inflated prices for branded Loestrin 24.

8. Having successfully forestalled generic competition until the expiration of the '394 Patent in July 2014, Warner Chilcott began implementing a plan to create additional barriers to competition. Brand name manufacturers frequently try to obstruct generic competition and preserve monopoly profits by making modest reformulations to the branded drug that offer little or no therapeutic advantages, a tactic called "product hopping." Warner Chilcott attempted a "product hop" by creating a follow-on branded product called Lo Loestrin Fe ("Lo Loestrin") which is patent protected until February 2029, and then attempted to herd all Loestrin 24 users to this new product.

9. Lo Loestrin provides no appreciable medical, convenience, or other benefits to patients as compared to Loestrin 24. To the contrary, scientific studies have shown that Lo Loestrin is less beneficial in many respects than Loestrin 24. Studies show that women have a 60% greater chance of becoming pregnant while taking Lo Loestrin as compared to Loestrin 24. Despite this, to perpetuate its market monopoly, Warner Chilcott instructed its sales representatives to urge doctors to switch Loestrin 24 users to Lo Loestrin.

10. Absent the unlawful payments from Warner Chilcott to Watson and Lupin to delay the launch of their generic versions of Loestrin 24, Warner Chilcott would never have begun selling Lo Loestrin, or if it had, it would have made very few sales given its inferior efficacy. It is well established in the pharmaceutical industry that if generic versions of the original brand product enter the market before the branded follow-on product, the latter will make very few sales unless it offers substantial, demonstrable medical benefits to consumers. Lo Loestrin offers no such benefits. Thus, Warner Chilcott's ploy of switching prescriptions to Lo Loestrin depended on launching Lo Loestrin before generic versions of Loestrin 24 were available. Absent Warner Chilcott's unlawful payments to Watson and Lupin, generic Loestrin 24 would have been available long before the FDA approved Lo Loestrin for sale, and Warner Chilcott either would not have launched Lo Loestrin or would have generated few sales of Lo Loestrin.

11. The FDA granted final approval to Watson's generic version of Loestrin 24 in September 2009. Absent the Defendants' anticompetitive scheme and agreements, a generic version of Loestrin 24 would have been available to Plaintiffs and Class Members in the United States as early as this date. Other generic versions of Loestrin 24 would have followed, driving generic prices down even further. These cheaper generic versions of Loestrin 24 would have been purchased by Plaintiffs and the Class Members. Instead, since September 2009, they were forced to pay supra-competitive prices for Loestrin 24.

12. Due to Warner Chilcott's unlawful and anticompetitive "product hop," Warner Chilcott was able to substantially reduce the number of Loestrin 24 prescriptions available for generic substitution by encouraging the switch to the less effective Lo Loestrin.

13. The purpose and result of Defendants' unlawful scheme and agreements was to: (a) block and delay the entry of less expensive generic oral contraceptives comprising 24 norethindrone acetate/ethinyl estradiol (1mg/20mcg) tablets and four ferrous fumarate tablets in the United States; (b) allow Warner Chilcott to fix, raise, maintain or stabilize the price of Loestrin products at supra-inflated rates; and (c) create and perpetuate a monopoly by allocating

100% of the United States market for oral contraceptives comprising 24 norethindrone acetate/ethinyl estradiol (1mg/20mcg) tablets and four ferrous fumarate tablets market to Warner Chilcott.

14. Defendants' unlawful and anticompetitive scheme and agreements have netted Defendants hundreds of millions of dollars in monopoly profits.

15. The unlawful and anticompetitive activities alleged in this Complaint constitute conspiracies and/or agreements to unreasonably restrain trade in violation of Section 1 of the Sherman Act, 15 U.S.C. §1 and also violates state antitrust and unfair and deceptive trade practices laws of Tennessee, Florida and North Carolina. The conduct is also violative of common law unjust enrichment.

16. For the above violations of state law, Plaintiffs seek compensatory and/or treble damages and equitable relief for continuing violations of state antitrust and/or consumer protection laws on behalf of a class of all consumers and third-party payors (the "End-Payor Subclasses") in States of Florida, Tennessee and North Carolina who purchased or paid for branded and/or generic Loestrin 24, other than for re-sale, since September 2009. Plaintiffs also seek an injunction pursuant to Section 16 of the Clayton Act, 15 U.S.C. §26, enjoining the continuation of the anticompetitive scheme and agreements on behalf of a class of all consumers and third-party payors (the "End-Payor Global Class") in the United States who purchased or paid for branded and/or generic Loestrin 24, other than for re-sale, since September 2009. Unless enjoined, Defendants' unlawful conduct will continue unchecked and Plaintiffs and the End-Payor Global and Subclasses will continue to bear the financial brunt of Defendants' antitrust violations.

PARTIES

A. Plaintiffs

17. Plaintiff Denise Loy is an adult, individual consumer, residing in Indian Harbor Beach, Florida. Plaintiff Loy has purchased and/or provided reimbursement for some or all of the purchase price of Loestrin 24, other than for re-sale (and will purchase generic Loestrin 24

other than for re-sale once it becomes available), at supra-competitive prices during the Class Period, and has thereby been injured. Plaintiff Loy purchased and took Loestrin 24 from approximately June 2011 until last month. If a generic alternative to Loestrin 24 had been available during the Class Period, Plaintiff Loy would have purchased the cheaper generic alternative rather than the branded Loestrin 24.

18. Plaintiff Melissa Chrestman is an adult, individual consumer, residing in Goodlettsville, Tennessee. Plaintiff Chrestman has purchased and/or provided reimbursement for some or all of the purchase price of Loestrin 24, other than for re-sale (and will purchase generic Loestrin 24 other than for re-sale once it becomes available), at supra-competitive prices during the Class Period, and has thereby been injured. Plaintiff Chrestman purchased and took Loestrin 24 from at least November 2012 until last month. If a generic alternative to Loestrin 24 had been available during the Class Period, Plaintiff Chrestman would have purchased the cheaper generic alternative rather than the branded Loestrin 24.

19. Plaintiff Mary Alexander is an adult, individual consumer, residing in Granite Quarry, North Carolina. Plaintiff Alexander has purchased and/or provided reimbursement for some or all of the purchase price of Loestrin 24, other than for re-sale (and will purchase generic Loestrin 24 other than for re-sale once it becomes available), at supra-competitive prices during the Class Period, and has thereby been injured. Plaintiff Alexander purchased and took Loestrin 24 from at least April 2011 through August 2013. If a generic alternative to Loestrin 24 had been available during the Class Period, Plaintiff Alexander would have purchased the cheaper generic alternative rather than the branded Loestrin 24.

B. Defendants

20. Defendant Warner Chilcott Public Limited Company is a company organized and existing under the laws of Ireland, and has its principal place of business at 1 Grand Canal Square, Docklands Dublin 2, Ireland L2 00000.

21. Defendant Warner Chilcott Company, LLC is a limited liability company organized and existing under the laws of the Commonwealth of Puerto Rico, and has its principal

place of business at Union St., Road 195, Km 1.1, Fajardo, Puerto Rico. This defendant holds an approved New Drug Application from the FDA for a formulation of oral contraceptives comprising 24 norethindrone acetate/ethinyl estradiol (1mg/20mcg) tablets and four ferrous fumarate tablets, which it sells throughout the United States under the brand name Loestrin 24 Fe. This defendant is a wholly owned subsidiary of Warner Chilcott PLC.

22. Defendant Warner Chilcott Holdings Company III, Ltd. is a privately-owned company organized and existing under and the laws of Bermuda, and has its office and principal place of business located at 100 Enterprise Drive, Rockaway, New Jersey 07866.

23. Defendant Warner Chilcott Corporation is a corporation organized and existing under the laws of Delaware, and has its principal place of business at 100 Enterprise Drive, Rockaway, New Jersey 07866.

24. Defendant Warner Chilcott (US), LLC is a limited liability company organized and existing under the laws of Delaware, and has its principal place of business at 100 Enterprise Drive, Rockaway, New Jersey 07866.

25. Defendant Warner Chilcott Sales (US), LLC is a limited liability company organized and existing under the laws of Delaware, and has its principal place of business at 100 Enterprise Drive, Rockaway, New Jersey 07866.

26. Defendant Warner Chilcott Laboratories Ireland Limited is a company organized and existing under the laws of the Republic of Ireland, and has its principal place of business at Union St., Road 195, Km 1.1, Fajardo, Puerto Rico.

27. Defendant Warner Chilcott Company, Inc., is a company organized and existing under the laws of the Commonwealth of Puerto Rico, and has its principal place of business at Union St., Road 195, Km 1.1, Fajardo, Puerto Rico.

28. The above defendants are collectively referred to herein as "Warner Chilcott." Warner Chilcott is engaged in the worldwide marketing, production and distribution of pharmaceutical products, including in this judicial district.

29. Actavis, Inc. is a company organized and existing under the laws of Nevada, and has its principal place of business at 400 Interplace Parkway, Parsippany, New Jersey 07054. Effective on or about January 24, 2013, Watson Pharmaceuticals, Inc. changed its name to Actavis, Inc.

30. Watson Pharmaceuticals, Inc. is a company organized and existing under the laws of Nevada, and has its principal place of business at 400 Interplace Parkway, Parsippany, New Jersey 07054. Effective on or about January 24, 2013, Watson Pharmaceuticals, Inc. changed its name to Actavis, Inc.

31. Watson Laboratories, Inc. is a company organized and existing under the laws of Nevada, and has its principal place of business at 311 Bonnie Circle, Corona, California 92880. Watson Laboratories, Inc. is a wholly-owned subsidiary of Watson Pharmaceuticals, Inc., which is now Actavis, Inc.

32. Actavis, Inc., Watson Pharmaceuticals, Inc. and Watson Laboratories, Inc. are collectively referred to herein as "Watson." Watson is engaged in the worldwide marketing, production and distribution of generic pharmaceutical products, including in this judicial district.

33. Lupin Ltd. is a company organized and existing under the laws of India, and has its principal place of business at B/4 Laxami Towers, Branda Kurla Complex, Bandra (East), Mumbai, Maharashtra 400 051, India.

34. Lupin Pharmaceuticals Inc. is a corporation organized and existing under the laws of Virginia, and has its principal place of business at Harbor Place Tower, 111 South Calvert Street, 21st floor, Baltimore, Maryland 21202. Lupin Pharmaceuticals Inc. is a wholly-owned subsidiary of Lupin Ltd.

35. Lupin Ltd. and Lupin Pharmaceuticals Inc. are collectively referred to herein as "Lupin." Lupin is engaged in the worldwide marketing, production and distribution of generic pharmaceutical products, including in this judicial district.

36. All of Defendants' actions described in this Complaint are part of, and in furtherance of, the unlawful conduct alleged herein, and were authorized, ordered, and/or done

by Defendants' various officers, agents, employees, or other representatives while actively engaged in the management of Defendants' affairs (or that of their predecessors-in-interest) within the course and scope of their duties and employment, and/or with the actual, apparent, and/or ostensible authority of Defendants.

JURISDICTION AND VENUE

37. This Court has jurisdiction over this action pursuant to 28 U.S.C. §1332(d) because this is a class action in which the aggregate amount in controversy exceeds $5,000,000 and at least one member of the putative class is a citizen of a state different from that of one of the Defendants.

38. This Court also has jurisdiction over this matter pursuant to 15 U.S.C. §26 and 28 U.S.C. §§ 1331 and 1337 because Plaintiffs bring claims under Section 16 of the Clayton Act, 15 U.S.C. §26, for injunctive and equitable relief to remedy Defendants' violations of Section 1 of the Sherman Antitrust Act, 15 U.S.C. § 1. The Court has supplemental jurisdiction over Plaintiffs' pendent state law claims pursuant to 28 U.S.C. § 1367. Additionally, pursuant to 28 U.S.C. § 1407, the Judicial Panel on Multidistrict Litigation created MDL 2472 to be presided over by the Hon. William E. Smith of the District of Rhode Island. This matter properly falls under the jurisdiction of MDL 2472.

39. Venue is appropriate within this district under Section 12 of the Clayton Act, 15 U.S.C. § 22, and 28 U.S.C. § 1391(b) and (c), because Defendants transact business within this district and the interstate trade and commerce, hereinafter described, is carried out, in substantial part, in this district.

INDUSTRY BACKGROUND

A. Characteristics of the Prescription Pharmaceutical Marketplace

40. Markets function best when the person responsible for paying for a product is also the person who chooses which product to purchase. In situations where the same person both chooses and pays for the product, the price of the product plays an appropriate role in the

person's product choice. In such a scenario, the manufacturers have an incentive to lower the prices of their products to ensure consumers select their products.

41. The pharmaceutical marketplace, however, is characterized by a "disconnect" between the payment obligation and the product selection. Many prescription drugs, including Loestrin 24, can only be dispensed via a prescription from a physician. In these situations, the patient (and in most cases the patient's insurer) has the obligation to pay for the pharmaceutical product, but the patient's doctor chooses which product the patient will buy.

42. Warner Chilcott and other brand manufacturers of prescription pharmaceutical products exploit this price disconnect to obtain or maintain market power in the sale of a particular pharmaceutical composition. Brand manufacturers employ large forces of sales representatives to visit doctors' offices and persuade them to prescribe their branded products. The sales representatives do not advise doctors of the cost of the branded products. Moreover, studies show that doctors typically are unaware of the relative costs of brand pharmaceuticals, and even when aware of the relative costs, they are insensitive to price differences because they do not have to pay for the products. The result is a marketplace in which price plays a comparatively unimportant role in product selection by physicians.

43. The relative unimportance of price in the pharmaceutical marketplace reduces what economists call the price elasticity of demand – the extent to which unit sales go down when price goes up. This reduced price elasticity in turn gives brand manufacturers the ability to raise prices substantially above marginal cost without losing so many sales as to make the price increase unprofitable. The ability to profitably raise prices substantially above marginal cost is what economists and antitrust courts refer to as market power. The result of the market imperfections and marketing practices described above allows brand manufacturers to gain and maintain market power with respect to particular branded prescription pharmaceuticals.

B. The Regulatory Structure for Approval of Generic Drugs and the Substitution of Generic Drugs for Brand Name Drugs

44. Under the Federal Food, Drug, and Cosmetic Act ("FDCA"), manufacturers that create a new drug must obtain FDA approval to sell the product by filing a New Drug Application ("NDA"). 21 U.S.C. §§ 301-392. The NDA must include specific data concerning the safety and effectiveness of the drug, as well as any information on applicable patents. 21 U.S.C. § 355(a), (b).

45. When the FDA approves a brand manufacturer's NDA, the manufacturer may list in the Orange Book any patents that the manufacturer believes could reasonably be asserted against a generic manufacturer that makes, uses, or sells a generic version of the brand drug before the expiration of the listed patents. After the FDA approves the NDA, the manufacturer may list in the Orange Book any patents within 30 days of their issuance. 21 U.S.C. § 355(b)(1), (c)(2).

46. The FDA relies completely on the brand manufacturer's truthfulness about patent validity and applicability, and it lacks the resources or authority to verify the manufacturer's patents for accuracy or trustworthiness. In listing patents in the Orange Book, the FDA merely performs a ministerial act.

1. The Hatch-Waxman Amendments

47. The Hatch-Waxman Amendments, enacted in 1984, simplified the regulatory scheme for prospective generic manufacturers by eliminating the need to file lengthy and costly NDAs. Instead, a manufacturer seeking approval to sell a generic version of a brand drug may file an Abbreviated New Drug Application ("ANDA").

48. The ANDA relies on the scientific findings of safety and effectiveness included in the brand manufacturer's original NDA, and must show the generic drug is both pharmaceutically equivalent and bioequivalent to the brand drug. Pharmaceutical equivalent generic drugs contain the same active ingredients, dosage form, route of administration, and strength as the brand drugs. Bioequivalence demonstrates that the active ingredient of the

proposed generic drug would be present in the blood of a patient to the same extent and for the same amount of time as the branded counterpart. 21 U.S.C. § 355(j)(8)(B).

49. A generic drug that is both pharmaceutically equivalent and bioequivalent to the branded counterpart is deemed "therapeutically equivalent" to the brand drug. The FDCA and Hatch-Waxman Amendments operate on the presumption that therapeutically equivalent drugs – that is, bioequivalent drug products containing identical amounts of the same active ingredients, having the same route of administration and dosage form, and meeting applicable standards of strength, quality, purity, and identity – may be substituted for one another. The FDA assigns an "AB" rating to generic drugs that are therapeutically equivalent to their brand-name counterparts.

50. The purpose of the Hatch-Waxman Amendments was to reduce healthcare expenses by expediting the entry of legitimate generic competitors into the market while simultaneously protecting pharmaceutical manufacturers' incentives to create new drugs.

51. The Hatch-Waxman Amendments achieved both goals with substantial increases in both the number of generic product launches and the profit margins for brand manufacturers. In 1983, before the Hatch-Waxman Amendments, only 35% of the top selling drugs with expired patents had generic alternatives; by 1998, nearly all did. In 1984, prescription drug revenue for branded and generic drugs totaled $21.6 billion; by 2009 total prescription drug revenue had soared to $300 billion.

2. Paragraph IV Certifications

52. To obtain FDA approval of an ANDA, a manufacturer must certify that the generic drug will not infringe any patents listed in the Orange Book. Under the Hatch-Waxman Amendments, a generic manufacturer's ANDA must contain one of four certifications:

i. no patent for the brand drug has been filed with the FDA (a "Paragraph I certification");

ii. the patent for the brand drug has expired (a "Paragraph II certification");

iii. the patent for the brand drug will expire on a particular date and the manufacturer does not seek to market its generic product before that date (a "Paragraph III certification"); or

iv. the patent for the brand drug is invalid or will not be infringed by the generic manufacturer's proposed product (a "Paragraph IV certification").

53. After the filing of a Paragraph IV certification by a generic manufacturer, the brand manufacturer can delay FDA approval of the ANDA simply by suing the ANDA applicant for patent infringement. If the brand manufacturer initiates a patent infringement action against the generic filer within 45 days of receiving notification of the Paragraph IV certification ("Paragraph IV Litigation"), the FDA will not grant final approval to the ANDA until the earlier of (a) the passage of 30 months, or (b) the issuance of a decision by a court that the patent is invalid or not infringed by the generic manufacturer's ANDA. During this period, while the FDA can grant "tentative approval" to the generic's ANDA, the generic manufacturer is not allowed to market its product. FDA may grant an ANDA tentative approval when it determines the ANDA would otherwise be ready for final approval but for the 30-month stay.

54. The first generic manufacturer to file an ANDA containing a Paragraph IV certification typically receives a period of protection from competition from other generic versions of the drug. This generic exclusivity period is designed to induce generic manufacturers to seek approval of generic alternatives to branded drugs. For Paragraph IV certifications made after December 2003, the first generic applicant receives 180 days of market exclusivity (unless some forfeiture event occurs). This effectively creates a duopoly between the brand company and the first-filing generic during this period. This 180-day exclusivity period is extremely valuable to generic companies. While only one generic is on the market, the generic price, while lower than the branded price, is much higher than after multiple generic competitors enter the market. Generics are usually at least 30% less expensive than their brand name counterparts when there is a single generic competitor, but this discount typically increases up to 80% when there are multiple generic competitors on the market. Being able to sell at the higher duopoly price for six months can be worth hundreds of millions of dollars to the generic manufacturer.

55. Brand manufacturers "game the system" by listing patents in the Orange Book (even if such patents are not eligible for listing) and suing any generic competitor that files an ANDA with a Paragraph IV certification (even if the new product does not actually infringe the brand's patent) just to delay final FDA approval of an ANDA for up to 30 months. The fact that generic firms in Paragraph IV litigation prevailed in 73% of the drug products studied (by obtaining a judgment of invalidity or non-infringement or voluntary dismissal by the patent holder) is striking evidence that brand manufacturers often sue generics under Hatch-Waxman simply to delay generic competition.

56. Another common tactic is for the first generic applicant to conspire with, or aid and abet, the brand manufacturer in gaming the system by using the 180-day period of generic market exclusivity given to the first generic applicant (called "parking") to delay not only its own market entry, but the market entry of all other generic manufacturers. This grants the brand manufacturer an additional 180-day period of brand name exclusivity, which can garner additional hundreds of millions of dollars.

57. The Medicare Prescription Drug, Improvement, and Modernization Act of 2003 ("MMA") was enacted, in part, to make it more difficult for brand and generic manufacturers to conspire to delay the start of the first-filer's 180-day period of generic market exclusivity. The MMA outlines a number of conditions under which an ANDA applicant forfeits its eligibility for 180-day exclusivity, allowing other ANDA filers to launch their generic products.

58. Under the "failure to market" provision, a first ANDA applicant forfeits its 180-day exclusivity if it fails to market its generic drug by the latter of: (a) the earlier of the date that is (i) 75 days after receiving final FDA approval; or (ii) 30 months after the date it submitted its ANDA; or (b) the date that is 75 days after the date as of which, as to each of the patents that qualified the first applicant for exclusivity (*i.e.*, as to each patent for which the first applicant submitted a Paragraph IV certification), at least one of the following has occurred: (i) a final decision of invalidity or non-infringement; (ii) a settlement order entering final judgment that

includes a finding that the patent is invalid or not infringed; or (iii) the NDA holder delists the patent from the FDA Orange Book.

59. Despite the MMA's intent, brand manufacturers and first-filing generics have adapted and can structure their settlements to intentionally skirt these forfeiture provisions. Manufacturers subvert the failure-to-market provisions and keep the 180-day exclusivity bottleneck in place by settling their litigation before a final judgment of invalidity or non-infringement can be entered with respect to each of the patents for which the first applicant submitted a Paragraph IV certification, or seeking a consent judgment that does not include a finding that all of the patents for which the first applicant submitted a Paragraph IV certification were invalid or not infringed. When that happens, to trigger forfeiture and gain access to the market, subsequent ANDA applicants are forced to obtain a judgment that all patents for which the first filing generic company filed Paragraph IV certifications are invalid or not infringed.

60. Brand and generic manufacturers can structure their settlements in a way that grants 180 days of exclusivity to the generic even where it is likely that the generic has forfeited that exclusivity under one of the applicable MMA forfeiture provisions. This results in a windfall to the generic and a subversion of the regulatory scheme. Because the FDA will not typically make a formal 180-day exclusivity determination until another generic applicant has received final approval and is ready to launch, settlements that retain de facto exclusivity – even where it should be forfeit *de jure* under the MMA – dissuade subsequent generic applicants from trying to obtain a court judgment of invalidity and/or infringement that would trigger the start of the 180 day period.

61. These "pay-to-delay" settlement arrangements between brand and potential generic competitors have a significant, adverse financial impact on consumers. The FTC estimates these "pay-to-delay" arrangements cost consumers $3.5 billion annually. The number of these "pay-to-delay" agreements has increased dramatically over the past few years from three in 2005 to 28 such agreements in 2012 alone.

62. While increasing in numbers, these "pay-to-delay" arrangements are not the normal method of resolving patent disputes between brand and generic competitors. From 2004 – 2009, 218 patent issue settlement agreements between brand and generic competitors were reached. Seventy percent of these settlements (152) did not involve any "pay-to-delay" arrangements.

C. The Economy of Generic Drugs

63. Generic versions of brand name drugs contain the same active ingredient, and are determined by the FDA to be just as safe and effective as their brand name counterparts. The only material difference between generic and brand name drugs is their price. Generic versions typically cost 30% less than the brand drug when there is a single generic competitor on the market and as much as 80% less when there are multiple generic competitors. The launch of a generic drug is usually associated with huge cost savings for all drug purchasers. The Federal Trade Commission ("FTC") estimates that in a mature generic market (about one year after market entry), the generic versions comprise over 90% of the total market demand and sell for 15% of the price of the brand name product.

64. Due to the price differentials between brand and generic drugs, pharmacists traditionally use the cheaper generic version when available for the prescribed brand-name drug. Every state has adopted substitution laws that either require or permit pharmacies to substitute generic equivalents for branded prescriptions (unless the prescribing physician has specifically ordered otherwise by writing "dispense as written" or similar language on the prescription).

65. The use of generic alternatives is encouraged at every link in the prescription drug chain. As a result of federal reimbursement rules and the industry pricing structure, pharmacies typically earn a higher markup on generics than on brands. Private health insurers similarly offer direct incentives to pharmacies to substitute cheaper generic products for more expensive branded ones. Health insurers are contractually obligated to pay for the bulk of their members' prescriptions, whether filled with branded or generic drugs, so they offer their members lower

copays for generic drugs to encourage their use. Members also face the threat of increased health insurance premiums if branded prescription drug costs continue to rise.

66. Generic competition enables all members of the proposed Class to: (a) purchase generic versions of the drug at substantially lower prices; and/or (b) purchase the brand drug at a reduced price.

67. Until a generic version of the brand drug enters the market, the brand manufacturer can continue to profitably charge supra-competitive prices. As a result, brand manufacturers such as Warner Chilcott have a huge financial incentive to delay the introduction of generic competition into the market, including by use of unlawful and anticompetitive tactics such as "pay-to-delay" or "reverse payment" agreements or "product hopping."

D. The Impact of Authorized Generics

68. The 180-day marketing exclusivity to which first-filer generics may be entitled does not prevent a brand manufacturer from marketing its own generic alternative to the brand drug during that 180-day period. Such an "authorized generic" is chemically identical and therapeutically equivalent to the brand drug, but is sold as a generic product through either a brand manufacturer's subsidiary or through a third-party generic manufacturer.

69. Competition from an authorized generic during the 180-day exclusivity period substantially reduces the first-filer's revenue and drug prices for consumers. In a recent study, *Authorized Generic Drugs: Short-term Effects and Long-Term Impact* (August 2011), the FTC found that authorized generics capture a significant portion of sales, on average reducing the first-filer's revenues by approximately 50% during the 180-day exclusivity period. Although first-filing generic manufacturers make significantly less money when they must compete with an authorized generic during the first 180 days, consumers and other drug purchasers such as Plaintiffs and the End-Payor Global Class and Subclasses benefit from the lower prices caused by competition between the authorized generic and the first-filing generic.

70. Given the significant negative impact of an authorized generic on the first-filing generic's revenues, a brand manufacturer's agreement not to launch an authorized generic has

tremendous value to the generic manufacturer. Brand manufacturers have used such agreements as a way to pay the first-filer to delay entering the market. Such non-competition agreements deprive consumers and other drug purchasers, such as Plaintiffs and the End-Payor Global Class and Subclasses, of the lower prices resulting from two forms of competition: (1) among the branded and the generic products; and (2) between the generic products.

THE ANTICOMPETITIVE SCHEME: FILE "SHAM" PATENT INFRINGMENT SUITS AGAINST GENERIC COMPETITORS, THEN PAY THEM TO DELAY ENTRY

A. Warner Chilcott Files Paragraph IV Litigation Against Watson

71. On April 15, 2005, Warner Chilcott submitted NDA 21-871 seeking FDA approval to market what became known as Loestrin 24. The FDA approved the NDA on February 17, 2006.

72. In connection with its Loestrin 24 NDA, Warner Chilcott listed the '394 Patent in the FDA Orange Book as covering Loestrin 24 or a method of using Loestrin 24. The purported invention described in the '394 Patent is a method of female contraception, comprised of administering a combination of estrogen and progestin for 23-25 consecutive days of a 28-day cycle and is characterized by a reduced incidence of breakthrough bleeding. Warner Chilcott markets Loestrin 24 as an effective low dose birth control, with shorter, lighter periods that produce less bleeding.

73. Warner Chilcott is the fifth owner of the '394 Patent, which issued in September 1996 to the Eastern Virginia Medical School ("EVMS"). EVMS sold the application that became the '394 Patent to Warner Lambert, which was acquired by Pfizer in 2000. Galen Holdings PLC acquired the '394 Patent from Pfizer in March 2003. In July 2004, Galen Holdings, PLC changed its name to Warner Chilcott. Loestrin 24 is the purported commercial embodiment of the '394 Patent.

74. The active ingredients in Loestrin 24, the hormones norethindrone acetate and ethinyl estradiol, are not protected by any patent. Norethindrone and ethinyl estradiol have served as the active ingredients in oral contraceptives dating back to at least the early 1970s.

Warner Chilcott's Loestrin Fe 1/20 product, which contains tablets identical to those used in Loestrin 24, was approved by the FDA on April 30, 1973. The only difference between the '394 Patent (and the corresponding Loestrin 24 product) and Loestrin Fe 1/20 is that the '394 Patent requires 23-25 days of tablets whereas the Loestrin 1/20 product was packaged in units of 21 active tablets.

75. Because the '394 Patent only claims a narrow method of using active ingredients that have been employed for decades as oral contraceptives, generic manufacturers were eager to apply for FDA approval to market generic versions of Loestrin 24 long before the expiration of the '394 Patent. The generic manufacturers correctly believed they could obtain a court ruling that the '394 Patent was invalid and unenforceable.

76. On or about April 17, 2006, Defendant Watson notified Warner Chilcott that Watson had filed ANDA No. 78-267 to market a generic version of Loestrin 24. Watson's notice letter included a Paragraph IV certification that the commercial manufacture, use and/or sale of its generic Loestrin 24 product would not infringe any valid claim of the '394 Patent.

77. On July 28, 2006, Warner Chilcott filed suit in the United States District Court for the District of New Jersey pursuant to Hatch-Waxman, and alleged that Watson's generic Loestrin 24 product would infringe the '394 Patent. Warner Chilcott filed the patent infringement case against Watson without regard to the merits of the case. Had the case proceeded to a litigated conclusion, it was very likely that Warner Chilcott would have lost. However, simply by filing the case, Warner Chilcott obtained automatic exclusion of Watson from the market for 30 months. Warner Chilcott's purpose in filing the case was to get the 30-month hiatus from generic competition, regardless of whether it ultimately won the case.

78. During the litigation, Watson conducted discovery supporting a host of defenses focusing on: (1) the enforceability of the '394 Patent; (2) the validity of the ''Patent; and (3) the strength of Warner Chilcott's infringement allegations.

79. On January 23, 2008, Watson submitted an Amended Answer and Counterclaim asserting that the claims of the '394 Patent are invalid under one or more of 35 U.S.C. §§ 102,

103 and 112. Watson asserted that the only difference between Loestrin 24 and Warner Chilcott's prior product, Loestrin Fe 1/20, was *de minimis*, particularly given that doctors routinely advised women using oral contraceptives to take more than 21 tablets in a row to delay the onset of menses that might otherwise occur at an inconvenient time. According to Watson, the claims of the '394 Patent were invalid because simply extending the regimen of a well-known prior art product by several days (from 21 days of active tablets to 23-25 days of active tablets) was obvious, having long been taught in the literature and practiced by women.

80. Watson alleged in its counterclaim that the '394 Patent was unenforceable under equitable doctrines, including inequitable conduct, common law fraud and unclean hands. Watson alleged, among other things, the applicants for the '394 Patent intentionally: (1) concealed from the PTO an invalidating public use of the claimed invention that occurred more than one year before the application filing date; (2) made false statements and withheld material information; and (3) withheld prior art that teaches an extended regimen of oral contraceptives (more than 21 days).

81. Loestrin Fe 1/20, which was known before the '394 Patent and was thus prior art, was known to have problems – a high incidence of breakthrough bleeding and an unacceptable failure rate – that the Loestrin Fe 1/20 patent suggested could be alleviated by extending the number of days per cycle during which the active pills were administrated. The Loestrin Fe 1/20 suggested that in low-dose oral contraceptives, the 7-day pill free period leads to follicular development, which may lead to pregnancy. Loestrin Fe 1/20 further suggested that using a 24-day regime of active pills while increasing the progestogen would provide improved suppression of follicular development. While Loestrin Fe 1/20 was often only administered for 21 days, the claims of the patent suggested 23-25 days. One of ordinary skill in the art would have been motivated to administer Loestrin Fe 1/20 for additional days to alleviate the known problems associated with its administration over 21 days. Accordingly, the '394 Patent could be subjected to invalidity as obvious in view of the prior art.

82. To prevent generic entry by relying on the '394 Patent, Warner Chilcott would need to defeat each of Watson's compelling arguments regarding invalidity and unenforceability and prove Watson infringed the '394 Patent. Instead Warner Chilcott decided to protect its monopoly by unlawfully paying Watson to withdraw its challenges to the validity and enforceability of the '394 Patent and delay its introduction of generic Loestrin 24.

83. But for Defendants' baseless patent infringement lawsuit, generic Loestrin 24 would have been available on the market as early as September 2009.

B. Warner Chilcott and Watson Enter Into an Unlawful "Pay-to-Delay" Agreement

84. Having obtained the goal of the patent infringement case against Watson – the 30-month stay of generic competition – Warner Chilcott decided to terminate the case. On or about January 12, 2009, just one month before the 30-month stay was to expire, Warner Chilcott and Watson entered into an agreement to delay entry of generic Loestrin 24 ("Watson "Pay-to-Delay" Agreement"). Pursuant to that Agreement, Warner Chilcott ended its '394 Patent litigation against Watson, and Watson dropped its counterclaims against Warner Chilcott. At the time of the unlawful agreement, the court adjudicating the patent case had not issued any substantive rulings regarding the merits of the case.

85. Under the Watson "Pay-to-Delay" Agreement, Watson agreed to delay launching its generic Loestrin 24 product until the earliest of: (1) January 22, 2014; (2) 180 days before a date on which Warner Chilcott granted rights to a third party to market a generic version of Loestrin 24 in the United States; or (3) the date on which another generic version of Loestrin 24 entered the market.

86. In return for Watson's agreement to drop its challenge to the '394 Patent and to delay entry of its generic Loestrin 24 product, Warner Chilcott agreed to pay Watson substantial sums. Warner Chilcott's payments to Watson under the Agreement took at least five forms.

87. First, the Watson Agreement prohibits Warner Chilcott from launching an authorized generic version of Loestrin 24 during Watson's first 180 days of marketing. The Agreement expressly prohibits Warner Chilcott or its affiliates from marketing or supplying, or

granting any third party rights to launch, an authorized generic during the 180-day period. Absent the Agreement, Warner Chilcott had the incentive and ability to launch an authorized generic version of Loestrin 24. Warner Chilcott has marketed authorized generic versions of several of its other branded drugs, including its oral contraceptive, Dovonex. Absent the entry of an authorized generic in the market, Watson could expect to make approximately double the unit sales, at a much higher price, at the expense of Plaintiffs and the End-Payor Class.

88. Second, Warner Chilcott agreed to grant to Watson a license to market Loestrin 24 everywhere in the world beginning January 22, 2014. The license to market Loestrin 24 both inside and outside the United States has substantially more value to Watson than a license to market the product only in the United States.

89. Third, the Watson Agreement provides that Warner Chilcott will pay Watson annual fees and a percentage of net sales above a specified level in connection with Watson's co-promotion of Femring, a Warner Chilcott hormone therapy product, beginning in 2009.

90. Fourth, the Agreement gives Watson the exclusive right to earn highly profitable brand sales of a Warner Chilcott oral contraceptive that was in late-stage development at the time of the Agreement. Watson now markets that product under the brand name Generess Fe, a chewable oral contraceptive. Watson has already earned tens of millions of dollars selling Generess Fe in the United States since its launch in May 2011.

91. Fifth, Warner Chilcott agreed not to grant a license to any other manufacturer to produce a generic version of Loestrin 24 until at least 180 days after Watson entered the market. Warner Chilcott thus guaranteed to Watson a period of 180 days of exclusivity as the only generic Loestrin 24 on the market (absent another generic manufacturer outlasting a 30-month stay or obtaining a court order permitting such entry). Watson had likely forfeited its entitlement to 180-day exclusivity under the Hatch-Waxman Act because it had failed to obtain tentative FDA approval to market generic Loestrin 24 within 30 months of submitting its ANDA in April 2006. Thus, the contractual exclusivity granted by Warner Chilcott had substantial value to Watson and precluded generic competition at the expense of Plaintiffs and other End-Payors.

92. If, for some reason, Watson did not forfeit its 180-day exclusivity, then its agreement with Warner Chilcott created a bottleneck that prevented FDA from approving any subsequent ANDA until 180 days after January 22, 2014. Either way, Defendants win at the expense of Plaintiffs and the End-Payor Class and Subclasses – either Watson obtained additional payment in the form of guaranteed six-month exclusivity or Watson agreed to delay its launch of generic Loestrin 24 in exchange for (other) payments, thereby creating an approval bottleneck that prevents other generics from entering the market until six months after Watson.

93. Warner Chilcott made these payments in exchange for Watson's agreement to delay generic competition to Loestrin 24 for over four years (or earlier under certain circumstances). Absent Watson's agreement to delay entry of generic Loestrin 24, Warner Chilcott would not have agreed to: (a) refrain from launching, or granting a license to others to launch, an authorized generic Loestrin 24 during Watson's first 180 days of marketing; (b) grant Watson a license to market Loestrin 24 globally beginning January 22, 2014; (c) designate Watson as a co-promotor of Femring; (d) grant Watson an exclusive license to market and sell Generess Fe; (e) guarantee Watson 180 days of exclusivity, which it had otherwise forfeited, to market a generic version of Loestrin 24; and/or (f) grant the price and/or other terms that it did under those provisions of the Agreement. Warner Chilcott paid Watson for delayed market entry of generic Loestrin 24.

C. Warner Chilcott Files Paragraph IV Litigation Against Lupin

94. As the first-filer, Watson had an opportunity to earn 180 days of exclusivity under the Hatch-Waxman Act. That circumstance created an economic incentive for other generic manufacturers to delay filing their own challenges to the '394 Patent while Watson litigated against Warner Chilcott. If Watson had obtained an order finding the patent invalid or unenforceable, other generic manufacturers would have benefitted from that ruling without having to incur the costs of patent litigation.

95. On or about July 2009, six months after the announcement of the agreement between Warner Chilcott and Watson, Lupin notified Warner Chilcott it had filed ANDA No.

091398 for the purpose of marketing generic versions of Loestrin 24. Lupin's notice letter included a Paragraph IV certification that the commercial manufacture, use and/or sale of its generic product would not infringe any valid and enforceable claim of the '394 Patent.

96. On or about September 9, 2009, Warner sued Lupin for infringement of the '394 Patent in the United States District Court for the District of Delaware (Civil Action No. 09-00673). Lupin answered the complaint on October 21, 2009, and alleged special defenses, including invalidity of the '394 Patent and non-infringement.

97. Warner Chilcott filed the case against Lupin without regard to its merits. Simply by filing the case, Warner Chilcott obtained automatic exclusion of Lupin from the market for 30 months. Warner Chilcott's sole purpose in filing the case was to obtain the 30-month hiatus from generic competition, regardless of whether it ultimately won the case. Indeed, had the case proceeded to a litigated conclusion, Warner Chilcott was very likely to have lost. Warner Chilcott's patent infringement lawsuit against Lupin was a "sham" filing.

98. During discovery, Lupin, like Watson before it, uncovered facts supporting a host of defenses that cast serious doubt on: (1) the enforceability of the '394 Patent (2) the validity of its claims; and (3) the strength of Warner Chilcott's infringement allegations.

99. To prevent generic entry by enforcing the '394 Patent, Warner Chilcott would have had to defeat each of Lupin's arguments regarding invalidity and unenforceability and prove that Lupin infringed the '394 Patent. Warner Chilcott instead decided to protect its monopoly by paying Lupin to withdraw its challenges to the validity and enforceability of the '394 Patent and delay its introduction of generic Loestrin 24.

D. Warner Chilcott and Lupin Enter an Exclusion Payment Agreement

100. Had Lupin obtained a court decision invalidating the '394 Patent, it would have broken the bottleneck caused by the Watson "Pay-to-Delay" Agreement. Instead, to extend and maintain its monopoly, Warner Chilcott made sure that Lupin, the second ANDA-filer for Loestrin 24, did not litigate the case conclusion. Before the court reached a determination on the issue of invalidity and/or non-infringement of the '394 Patent, Warner Chilcott paid Lupin to

drop its patent challenge and stay out of the market until after Watson was permitted to enter the market pursuant to the Watson "Pay-to-Delay" Agreement.

101. On or about October 10, 2010, before the close of fact discovery and before the court could issue any substantive rulings, Warner Chilcott entered into a non-competition agreement with Lupin ("Lupin 'Pay-to-Delay' Agreement") and dismissed the case. Pursuant to that Agreement, Lupin agreed to drop its challenge to the '394 Patent and to delay entry of its generic version of Loestrin 24 until July 22, 2014, the month that the '394 Patent is set to expire. In exchange, Warner Chilcott agreed to pay Lupin substantial sums. Warner Chilcott's payments to Lupin under the Lupin "Pay-to-Delay" Agreement took at least two forms.

102. First, the Lupin "Pay-to-Delay" Agreement granted to Lupin a non-exclusive license covering Femcon Fe, another branded oral contraceptive manufactured by Warner Chilcott, which permitted Lupin to begin marketing an authorized generic version of Femcon Fe, supplied by Warner Chilcott, in the United States beginning on the earlier of: (i) 180 days after Teva Pharmaceutical Industries, Ltd. (the first-filer with respect to Femcon Fe) entered the market with a generic equivalent to Femcon Fe; or (ii) January 1, 2013. Pursuant to the Lupin Agreement, Lupin in fact entered the market with generic Femcon Fe in October 2011, and since that time has made substantial sales of that product. But for the Lupin "Pay-to-Delay" Agreement, Lupin could not have begun making generic Femcon FE sales until the end of the 30-month stay in February 2012.

103. Second, the Lupin "Pay-to-Delay" Agreement gave Lupin the right to purchase and sell in the United States a generic version of Asacol 400 mg (a branded treatment for inflammatory bowel disease), to be supplied by Warner Chilcott, if a generic version of Asacol 400 mg is launched by another generic manufacturer in the United States.

104. Warner Chilcott made these payments in exchange for Lupin's agreement to delay generic competition to Loestrin 24 for more than two years (unless another generic entered the market first, which Warner Chilcott prevented through other agreements). Absent Lupin's agreement to delay entry into the market with generic Loestrin 24, Warner Chilcott would not

have agreed to: (a) grant to Lupin the non-exclusive license to make or sell generic Femcon Fe; (b) grant to Lupin the license to make or sell, under certain circumstances, a generic version of Asacol 400 mg; and/or (c) grant the price and/or other terms that it did under those provisions of the Agreement. Warner Chilcott paid Lupin for delayed market entry of generic Loestrin 24.

105. As described more fully below, Warner Chilcott delayed generic entry in order to both extend and protect its Loestrin 24 monopoly and to buy time to switch prescriptions to a follow-on branded version of Loestrin before generic Loestrin 24 became available.

THE ANTICOMPETITIVE SCHEME: SWITCH PRESCRIPTIONS FROM LOESTRIN 24 TO LO LOESTRIN

106. To exploit the market "disconnect" and maintain its monopoly and supra-competitive sales in the Loestrin market, Warner Chilcott needed to prevent the successful entry of generic Loestrin. In response to the competitive threat from generic Loestrin, Warner Chilcott devised a so-called "life cycle management" plan which involved, among other things, the rote filing of patent infringement cases regardless of their merit and unlawful pay-offs to generic manufacturers to delay entry. As part of the life cycle management plan, Warner Chilcott took an additional step to extend its monopoly: it made modifications to the Loestrin product that deliver no benefits to patients but nonetheless effectively shield substantial Loestrin sales from generic competition. Essentially Defendants fraudulently created a second, duplicative patent for the same drug covered by the first patent.

107. While awaiting the 30-month stays obtained by filing meritless patent lawsuits to expire, Warner Chilcott slightly altered the composition of its Loestrin product with the intent to render any generic versions of Loestrin inappropriate substitutes for branded Loestrin when the generic versions finally entered the market. Warner Chilcott designed this "product hop" in order to protect as many Loestrin sales as possible from generic competition.

108. On March 26, 2009, Warner Chilcott submitted an application to the FDA for approval to market a revised version of Loestrin (called "Lo Loestrin Fe"). Lo Loestrin was not, nor was it intended to be, a new and superior product to Loestrin 24. Rather, Lo Loestrin was

designed and marketed solely as a means to impair generic competition. The true purpose of Lo Loestrin is evidenced by the fact that Warner Chilcott delayed development and marketing of Lo Loestrin until just before generic competition was to hit the market.

109. Both Lo Loestrin and Loestrin 24 contain the same active ingredients. The only appreciable difference between the two is the frequency of dosing. Not only are there no appreciable medicinal benefits to Lo Loestrin, there are actually significant disadvantages to taking Lo Loestrin instead of Loestrin 24. Clinical studies indicate Lo Loestrin is far less effective at preventing pregnancy than Loestrin 24. These studies revealed the pregnancy rate (Pearl Index) for women using Lo Loestrin was 2.92 pregnancies per 100 women-years of use. This rate is more than 60% higher than the rate for Loestrin 24, which is 1.82. This, along with the well-documented difficulties and dangers inherent in transferring patients from one oral contraceptive to another, shows Lo Loestrin offers no real benefit to patients over Loestrin 24.

110. Because of its less efficacious nature, Warner Chilcott expected Lo Loestrin would cause the company to lose sales and revenue, clearly pointing to Lo Loestrin's effect of impairing generic competition as the real reason for its creation and launch.

111. It was essential to Warner Chilcott that it launch, and convert as many potential Loestrin 24 prescriptions as possible to, Lo Loestrin before generic versions of Loestrin 24 were available in the market. It is well established in the pharmaceutical industry that if generic versions of the original brand product enter the market before the branded follow-on product, the latter will make very few sales unless it offers substantial, demonstrable medical benefits to consumers. One brand manufacturer estimated it would make ten times more sales of its branded follow-on product if it beat generic versions of the original product onto the market. In a detailed inquiry into the pharmaceutical industry, the European Commission concluded that "it is of utmost importance for the originator company to bring the follow-on product on the market before the first product effectively loses exclusivity." European Commission, Final Report, p. 356 (8 July 2009), available at http://www.europanu.nl/id/vi6wcj7amsx3/pharmaceutical_sector_inquiry_fianl?start-006-00c=10.

112. Lo Loestrin offers no medical, convenience, or other benefits to consumers, as compared to Loestrin 24. Warner Chilcott's ploy of switching prescriptions to Lo Loestrin depended on launching Lo Loestrin before generic versions of Loestrin 24 were available. Beating the generics onto the market would allow Warner Chilcott to effectuate the shift to Lo Loestrin at a time when no competing manufacturer had the incentive or ability to counter Warner Chilcott's marketing message to doctors.

113. Absent Warner Chilcott's unlawful payments to Watson and Lupin to delay entry, generic Loestrin 24 would have been available long before the FDA approved Lo Loestrin for sale. Thus, in the absence of Warner Chilcott's unlawful payments to Watson and Lupin, Warner Chilcott would not have launched Lo Loestrin or, if it had, it would have made few sales.

114. Due to Warner Chilcott's anticompetitive scheme and unlawful payments to Watson and Lupin to delay entry, by the time generic Loestrin 24 is available in January 2014, the prescription base for Loestrin 24 will have been very substantially eroded.

ANTICOMPETITIVE EFFECTS OF THE SCHEME

115. Warner Chilcott's scheme and payments to suppress generic competition to Loestrin 24 substantially delayed the introduction of generic Loestrin 24 to the market and substantially diminished the sale of generic Loestrin 24. By delaying the onset of generic competition and reducing the prescription base, Defendants deprived would-be generic versions of the most efficient means of distribution under the governing statutory and regulatory regime, deprived consumers of the competitive pricing that generic competition creates and created an unlawful monopoly of the Loestrin 24 market (even if for only a finite time).

116. Warner Chilcott's overarching anticompetitive scheme, and the Generic Defendants' participation in it, delayed and substantially diminished the sale of generic Loestrin 24 in the United States and unlawfully enabled Warner Chilcott to sell Loestrin 24 at artificially inflated prices. Absent Defendants' illegal and anticompetitive conduct, generic manufacturers would have been able to enter the market unimpeded and compete on the merits against Loestrin 24 thereby giving consumers a cheaper alternative to brand Loestrin 24. Generic competitors

would also have been able to compete earlier, as early as September 2009, and additional generic competitors would have entered the market thereafter. Defendants' conduct unlawfully prevented purchasers of Loestrin 24 from obtaining the benefits of unimpaired generic competition.

117. Defendants' scheme and unlawful payments harmed Plaintiffs and End-Payors by depriving them of: (1) a free and competitive market in which manufacturers and distributors of generic drugs make decisions about challenging patents and entering markets free from the influence of unlawful payments; (2) the most cost efficient means of distribution; (3) a market with generic products which would result in substantially lower prices; (4) contrary to the purpose of the Hatch-Waxman Act, the anticompetitive scheme and payments have enabled Defendants to: (a) delay the entry of less expensive generic versions of Loestrin 24 in the United States; (b) fix, raise, maintain or stabilize the price of Loestrin 24; and (c) allocate 100% of the U.S. market for an oral contraceptive comprising 24 norethindrone acetate/ethinyl estradiol (1mg/20mcg) tablets and four ferrous fumarate tablets to Warner Chilcott.

118. But for the anticompetitive scheme: (i) Watson would have begun selling AB rated generic versions of Loestrin 24 on or shortly after receiving final FDA approval of its generic Loestrin 24 ANDA on September 1, 2009; (ii) an increasingly competitive market for oral contraceptives comprising 24 norethindrone acetate/ethinyl estradiol (1mg/20mcg) tablets and four ferrous fumarate tablets would have emerged; and (iii) Warner Chilcott would not have developed or marketed Lo Loestrin and switched a substantial portion of sales to that product and/or generic Loestrin 24 would have entered the market before Lo Loestrin, thereby impeding Warner Chilcott from switching prescriptions to Lo Loestrin.

119. Defendants' unlawful conduct has delayed and diminished the sale of generic Loestrin 24 in the United States, and unlawfully enabled Warner Chilcott to sell Loestrin 24 at artificially inflated, supra-competitive prices. But for Defendants' illegal conduct, generic competition to Loestrin 24 would have occurred already, because, at a minimum, Watson would

have already launched its generic version of Loestrin 24 and Warner Chilcott (or its designee) would have already entered the market with an authorized generic version of Loestrin 24.

120. Defendants' anticompetitive scheme resulted in millions of dollars in unlawful profit to Warner Chilcott.

121. As a consequence, Plaintiffs and other Class Members have sustained substantial losses and damage to their business and property in the form of overcharges, the exact amount of which will be the subject of proof at trial.

CLASS ACTION ALLEGATIONS

122. Plaintiffs bring this action on behalf of themselves and, under Fed. R. Civ. P. 23(a) and (b)(3), as representative of an End-Payor Global Class defined as follows:

> All persons or entities in the United States and its territories who purchased and/or paid for some or all of the purchase price for Loestrin 24 Fe and/or its AB-rated generic equivalents in any form, for consumption by themselves, their families, or their members, employees, insureds, participants, or beneficiaries (the "End-Payor Global Class"), other than for resale, during the period September 1, 2009 through and until the anticompetitive effects of Defendants' unlawful conduct cease. For purposes of the class definition, persons or entities "purchased" Loestrin 24 Fe or its generic equivalent if they paid or reimbursed some or all of the purchase price.

123. The following persons or entities are excluded from the proposed End-Payor Global Class:

a. Defendants and their officers, directors, management, employees, subsidiaries, or affiliates;

b. All governmental entities, except for government-funded employee benefit plans;

c. All persons or entities who purchased Loestrin 24 or its AB-rated generic equivalent for purposes of resale or directly from Defendants or their affiliates;

d. Fully insured health plans (i.e., plans that purchased insurance from another third-party payor covering 100% of the plan's reimbursement obligations to its members);

e. Any "flat co-pay" consumers whose purchases were paid in part by a third-party payor and whose co-payment was the same regardless of the retail purchase price; and

f. Any "brand loyalist" consumers or third-party payors who purchased Loestrin 24 and who did not purchase any AB-rated generic equivalent after such generics became available.

124. Plaintiff Chrestman brings this action on behalf of herself and, under Fed. R. Civ. P. 23(a) and (b)(3), as representative of the End-Payor Tennessee Subclass defined as follows:

> All persons or entities in the State of Tennessee who purchased and/or paid for some or all of the purchase price for Loestrin 24 Fe and/or its AB-rated generic equivalents in any form, for consumption by themselves, their families, or their members, employees, insureds, participants, or beneficiaries (the "End-Payor Tennessee Subclass"), other than for resale, during the period September 1, 2009 through and until the anticompetitive effects of Defendants' unlawful conduct cease. For purposes of the class definition, persons or entities "purchased" Loestrin 24 Fe or its generic equivalent if they paid or reimbursed some or all of the purchase price.

125. Plaintiff Loy brings this action on behalf of herself and, under Fed. R. Civ. P. 23(a) and (b)(3), as representative of the End-Payor Florida Subclass defined as follows:

> All persons or entities in the State of Florida who purchased and/or paid for some or all of the purchase price for Loestrin 24 Fe and/or its AB-rated generic equivalents in any form, for consumption by themselves, their families, or their members, employees, insureds, participants, or beneficiaries (the "End-Payor Florida Subclass"), other than for resale, during the period September 1, 2009 through and until the anticompetitive effects of Defendants' unlawful conduct cease. For purposes of the class definition, persons or entities "purchased" Loestrin 24 Fe or its generic equivalent if they paid or reimbursed some or all of the purchase price.

126. Plaintiff Alexander brings this action on behalf of herself, and under Fed. R. Civ. P. 23(a) and (b)(3), as representative of the End-Payor North Carolina Subclass defined as follows:

> All persons or entities in the State of North Carolina who purchased and/or paid for some or all of the purchase price for Loestrin 24 Fe and/or its AB-rated generic equivalents in any form, for consumption by themselves, their families, or their members, employees, insureds, participants, or beneficiaries (the "End-Payor North Carolina Subclass"), other than for resale, during the period September 1, 2009 through and until the anticompetitive effects of Defendants' unlawful conduct cease. For purposes of the class definition, persons or entities "purchased" Loestrin 24 Fe or its generic equivalent if they paid or reimbursed some or all of the purchase price.

127. The following persons or entities are excluded from the proposed End-Payor Subclasses:

a. Defendants and their officers, directors, management, employees, subsidiaries, or affiliates;

b. All governmental entities, except for government-funded employee benefit plans;

c. All persons or entities who purchased Loestrin 24 or its AB-rated generic equivalent for purposes of resale or directly from Defendants or their affiliates;

d. Fully insured health plans (i.e., plans that purchased insurance from another third-party payor covering 100% of the plan's reimbursement obligations to its members);

e. Any "flat co-pay" consumers whose purchases were paid in part by a third-party payor and whose co-payment was the same regardless of the retail purchase price; and

f. Any "brand loyalist" consumers or third-party payors who purchased Loestrin 24 and who did not purchase any AB-rated generic equivalent after such generics became available.

128. Members of the End-Payor Global and Subclasses are so numerous and geographically dispersed that joinder is impracticable. Plaintiffs believe the End-Payor Global and Subclasses include hundreds of thousands, if not millions, of consumers, and thousands of third-party payors. The End-Payor Global and Subclasses are readily identifiable from information and records that are required by law to be maintained by pharmacies, pharmaceutical benefit managers and managed care organizations, as well as those records in the possession of Defendants.

129. Plaintiffs' claims are typical of those of the members of the End-Payor Global and Subclasses. Plaintiffs and all members of the End-Payor Global and Subclasses were damaged by the same unlawful and anticompetitive conduct of Defendants, *i.e.*, they paid artificially inflated prices for Loestrin 24 and were deprived of the benefits of earlier and more robust competition from cheaper generic versions of Loestrin 24 as a result of Defendants' wrongful conduct.

130. Plaintiffs will fairly and adequately protect and represent the interests of the End-Payor Global and Subclasses. The interests of the Plaintiffs are aligned with, and not antagonistic to, those of the End-Payor Global and Subclasses.

131. Plaintiffs are represented by counsel experienced in the prosecution of class action antitrust litigation, and with particular experience in class action antitrust litigation involving pharmaceutical products.

132. Questions of law and fact common to the members of the End-Payor Global and Subclasses predominate over questions that may affect only individual class members because Defendants have acted on grounds generally applicable to the entire End-Payor Global and Subclasses, thereby making overcharge damages with respect to the End-Payor Global and Subclasses as a whole appropriate. Such generally applicable conduct is inherent to Defendants' wrongful conduct.

133. Questions of law and fact common to the End-Payor Global and Subclasses include, but are not limited to:

a. whether Defendants conspired to suppress generic competition to Loestrin 24;

b. whether Defendants Warner Chilcott and Watson entered into an unlawful agreement in restraint of trade;

c. whether, pursuant to the agreement, Watson agreed to delay its entry into the market with generic Loestrin 24;

d. whether, pursuant to the agreement, Warner Chilcott compensated Watson;

e. whether Warner Chilcott's compensation to Watson was for a purpose other than delayed entry of generic Loestrin 24;

f. whether Warner Chilcott's compensation to Watson was necessary to yield some procompetitive benefit that is cognizable and non-pretextual;

g. whether the agreement is *per se* illegal, illegal under a "quick look" analysis, or illegal under the rule of reason;

h. whether Defendants Warner Chilcott and Lupin entered into an unlawful agreement in restraint of trade;

i. whether, pursuant to the agreement, Lupin agreed to delay its entry into the market with generic Loestrin 24;

j. whether, pursuant to the agreement, Warner Chilcott compensated Lupin;

k. whether Warner Chilcott's compensation to Lupin was for a purpose other than delayed entry of generic Loestrin 24;

l. whether Warner Chilcott's compensation to Lupin was necessary to yield some procompetitive benefit that is cognizable and non-pretextual;

m. whether the agreement is *per se* illegal, illegal under a "quick look" analysis, or illegal under the rule of reason;

n. whether Warner Chilcott filed the patent litigations against the generic manufacturers without regard to the litigations' merit, in order to obtain the benefit of the automatic 30-month stay;

o. whether, absent the delay caused by Defendants' unlawful payments, Warner Chilcott would have launched and marketed Lo Loestrin;

p. whether Warner Chilcott introduced, priced, and marketed Lo Loestrin in order to diminish the prescription base of Loestrin 24;

q. whether Warner Chilcott possessed market power over Loestrin 24;

r. whether the law requires definition of a relevant market when direct proof of market power is available and, if so, the definition of the relevant market;

s. whether the activities of Defendants as alleged herein have substantially affected interstate commerce;

t. whether, and to what extent, Defendants' conduct caused antitrust injury (i.e., overcharges) to Plaintiffs and class members; and

u. the quantum of aggregate overcharge damages to the End-Payor Global and Subclasses

134. Class action treatment is a superior method for the fair and efficient adjudication of the controversy. Such treatment will permit a large number of similarly situated persons to prosecute their common claims in a single forum simultaneously, efficiently, and without the unnecessary duplication of evidence, effort, or expense that numerous individual actions would engender. The benefits of proceeding through the class mechanism, including providing injured

persons or entities a method for obtaining redress on claims that could not practicably be pursued individually, substantially outweighs potential difficulties in management of this class action.

135. Plaintiffs know of no special difficulty to be encountered in the maintenance of this action that would preclude its maintenance as a class action.

INTERSTATE AND INTRASTATE COMMERCE

136. At all material times, Warner Chilcott manufactured, promoted, distributed, and sold substantial amounts of Loestrin 24 in a continuous and uninterrupted flow of commerce across state and national lines and throughout the United States.

137. At all material times, Defendants transmitted funds, as well as contracts, invoices and other forms of business communications and transactions, in a continuous and uninterrupted flow of commerce across state and national lines in connection with the sale of Loestrin 24 and/or AB-rated bioequivalents.

138. In furtherance of their efforts to monopolize and restrain competition in the market for Loestrin 24 and its generic equivalents, Defendants employed the United States mails and interstate and international telephone lines, as well as means of interstate and international travel. Defendants' activities were within the flow of, and have substantially affected, interstate commerce.

139. Defendants' anticompetitive conduct had substantial intrastate effects in that, among other things, retailers within each state were foreclosed from offering less expensive generic Loestrin 24 to end-payors inside each respective state. The foreclosure of generic Loestrin 24 directly impacted and disrupted commerce for end-payors within each state.

MARKET POWER AND MARKET DEFINITION

140. At all relevant times, Warner Chilcott had market power with respect to oral contraceptives comprising 24 norethindrone acetate/ethinyl estradiol (1mg/20mcg) tablets and four ferrous fumarate tablets because it had the power to maintain the price of the drug. Warner Chilcott sold Loestrin 24 at supra-competitive levels without losing sufficient sales to make the supra-competitive price unprofitable.

141. A small but significant, non-transitory price increase above the competitive level for Loestrin 24 by Warner Chilcott would not have caused a loss of sales sufficient to make the price increase unprofitable.

142. At competitive price levels, Loestrin 24 does not exhibit significant, positive cross-elasticity of demand with respect to price with any product other than AB-rated generic versions of Loestrin 24.

143. Other branded oral contraceptives and generic versions of those other branded oral contraceptives are not AB-rated to Loestrin 24 and cannot be automatically substituted for Loestrin 24 by pharmacists. Thus, other oral contraceptives are not economic substitutes for, nor reasonably interchangeable with, Loestrin 24.

144. Different formulations of oral contraceptives dramatically differ in their efficacy, safety and complications. The differing efficacy, safety and complications of different oral contraceptives play a critical role in doctors' selection of the most appropriate oral contraceptive for a particular patient. The FDA does not consider these products bioequivalent, and there is variation in the dosage of the active ingredients.

145. Although a physician may initially choose among a number of different oral contraceptive pills, once the physician and patient find one that is well-tolerated, it is unlikely the patient will switch to a different oral contraceptive based on variations of price of 10% or less. Doctors generally select an oral contraceptive for their patients primarily based on the clinical and pharmacological attributes of the drug and the relevant characteristics of the patient, rather than on the basis of price.

146. Physicians and patients prefer Loestrin 24 to other products designed to prevent pregnancy. In part due to its use and efficacy in preventing pregnancy while simultaneously causing shorter, lighter periods, Loestrin 24 is significantly differentiated from all products other than AB-rated generic versions of Loestrin 24.

147. The existence of other products designed to prevent pregnancy has not significantly constrained Warner Chilcott's pricing of Loestrin 24. At all relevant times, Warner

Chilcott's price for Loestrin 24 has been at least 60% above its marginal cost of production, and at least 40% above its marginal cost including marketing costs. Warner Chilcott has never lowered the price of Loestrin 24 in response to the pricing of other branded oral contraceptives (or the generic versions of those other branded oral contraceptives).

148. Warner Chilcott needed to control only Loestrin 24 and its AB-rated generic equivalents, and no other products, to maintain the price of Loestrin 24 profitably at supra-competitive prices. Only the market entry of a competing, AB-rated generic version of Loestrin 24 would render Warner Chilcott unable to maintain supra-competitive prices for Loestrin 24. The entry of other branded oral contraceptives (or generic versions of those other brands) would not and did not take substantial sales from Loestrin 24 or cause Warner Chilcott to lower its price.

149. Warner Chilcott was fully aware that entry of a generic version of Loestrin 24 would have a significant impact on the market. Warner Chilcott knew that entry of generic Loestrin 24 would immediately cause branded Loestrin 24 to lose well more than half of its unit sales. Likewise, Watson was aware its generic version of Loestrin 24 would take essentially all of the sales from branded Loestrin 24 but few if any sales from other branded oral contraceptives (or generic versions of those other brands). Lupin predicted the same with respect to its generic version of Loestrin 24.

150. Warner Chilcott, Watson, and Lupin were all aware the competitive impact of a generic version on branded Loestrin 24 would be substantial. This includes knowledge that generic Loestrin 24 would result in hundreds of millions of dollars of savings to consumers.

151. At all relevant times, Warner Chilcott has sold Loestrin 24 at prices well in excess of marginal costs, and in excess of the competitive price, and enjoyed high profit margins.

152. Warner Chilcott had, and exercised, the power to exclude and restrict competition to Loestrin 24 and AB-rated bioequivalents.

153. Warner Chilcott, at all relevant times, enjoyed high barriers to entry with respect to competition in the relevant product market due to patent and other regulatory protections and high costs of entry and expansion.

154. To the extent that Plaintiffs are legally required to prove market power circumstantially by first defining a relevant product market, Plaintiffs allege that the relevant product market is oral contraceptives comprising 24 norethindrone acetate/ethinyl estradiol (1mg/20mcg) tablets and four ferrous fumarate tablets (*i.e.*, Loestrin 24 and its AB-rated generic equivalents). During the relevant time, Warner Chilcott has been able to profitably maintain the price of oral contraceptives comprising 24 norethindrone acetate/ethinyl estradiol (1mg/20mcg) tablets and four ferrous fumarate tablets well above competitive levels.

155. The relevant geographic markets are the United States and its territories as well as the States of Florida, Tennessee and North Carolina.

156. At all relevant times, Warner Chilcott's market share in the relevant market was and remains 100%.

MARKET IMPACT AND CLASS DAMAGES

157. Defendants' unlawful and anti-competitive acts and practices had the purpose and effect of unreasonably restraining and harming competition by protecting Loestrin 24 from any generic competition. This allowed Warner Chilcott to maintain a monopoly and exclude competition in the market for oral contraceptives comprising 24 norethindrone acetate/ethinyl estradiol (1mg/20mcg) tablets and four ferrous fumarate tablets, to the detriment of all persons who paid for brand name Loestrin 24 during the relevant period.

158. Absent Defendants' unlawful and anti-competitive conduct, Watson would have entered the market with its generic Loestrin 24 as early as September 1, 2009, the date its ANDA 78-267 received final FDA approval. Lupin and other generic manufacturers would have entered the market with additional generic versions of Loestrin 24 approximately 180 days thereafter.

159. Defendants' anticompetitive conduct had the purpose and effect of injuring and unreasonably restraining competition by protecting Loestrin 24 from generic competition.

Defendants' actions allowed Defendants to maintain a monopoly and exclude competition in the market for Loestrin 24.

160. Watson and Lupin have extensive experience in the pharmaceutical industry, including obtaining approval for ANDAs and marketing generic pharmaceutical products, manufacturing commercial launch quantities adequate to meet market demand, and, where appropriate, paying and receiving consideration for selective waiver and/or relinquishment of 180-day first-to-file marketing exclusivities.

161. Defendants' anticompetitive conduct, which delayed introduction into the United States marketplace of generic versions of Loestrin 24, has caused Plaintiffs and the End-Payor Global and Subclasses to pay more than they otherwise would have paid for oral contraceptives comprising 24 norethindrone acetate/ethinyl estradiol (1mg/20mcg) tablets and four ferrous fumarate tablets absent Defendants' illegal conduct.

162. Typically, generic versions of brand drugs are initially priced significantly below the corresponding brand drug to which they are AB-rated. Thus, after generic versions are available, end-payors immediately substitute generic versions of the drug for some or all of their purchases. As the generic market becomes more mature (additional generic manufacturers enter the market), prices drop even further due to increased competition among the generic manufacturers. As a result, the brand drug loses even more of its market share to generic versions of the drug. This price competition enables all purchasers of the drug to: (a) purchase generic versions of a drug at substantially lower prices, and/or (b) purchase the brand drug at a reduced price. Consequently, brand manufacturers have a keen financial interest in delaying and impairing generic competition, and purchasers experience substantial cost inflation from that delay and impairment.

163. But for Defendants' anticompetitive conduct Plaintiffs and End-Payor Global and Subclass Members would have paid less for oral contraceptives comprising 24 norethindrone acetate/ethinyl estradiol (1mg/20mcg) tablets and four ferrous fumarate tablets by: (a) substituting purchases of less-expensive AB-rated generic Loestrin 24 for their purchases of

more-expensive branded Loestrin; (b) receiving discounts on their remaining branded Loestrin 24 purchases; and (c) having access to lower priced generic Loestrin 24 sooner.

164. Due to Defendants' anticompetitive conduct, other generic manufacturers were discouraged from and/or delayed in (a) developing generic versions of Loestrin 24, and/or (b) challenging the validity or infringement of the '394 Patent in court.

165. During the Class Period, Plaintiffs and other End-Payor Global and Subclass Members purchased substantial amounts of Loestrin 24. As a result of Defendants' unlawful conduct, Plaintiffs and other End-Payor Global and Subclass Members were compelled to pay, and did pay, artificially inflated prices for oral contraceptives comprising 24 norethindrone acetate/ethinyl estradiol (1mg/20mcg) tablets and four ferrous fumarate tablets. Plaintiffs and other End-Payor Global and Subclass Members paid prices for oral contraceptives comprising 24 norethindrone acetate/ethinyl estradiol (1mg/20mcg) tablets and four ferrous fumarate tablets that were substantially greater than the prices that they would have paid absent the illegal conduct alleged herein, because: (1) End-Payor Global and Subclass Members were deprived of the opportunity to purchase lower-priced generic Loestrin 24 instead of expensive brand Loestrin 24; and (2) End-Payor Global and Subclass Members paid artificially inflated prices for Loestrin 24.

166. As a consequence, Plaintiffs and End-Payor Global and Subclass Members sustained substantial losses and damage to their business and property in the form of overcharges, the exact amount of which will be the subject of proof at trial.

167. Thus, Defendants' unlawful conduct deprived Plaintiffs and the End-Payor Global and Subclasses of the benefits of competition that the antitrust laws were designed to ensure.

ANTITRUST IMPACT

168. During the relevant period, Plaintiffs and the End-Payor Global and Subclass Members paid for substantial amounts of brand Loestrin 24 and/or paid for substantial amounts of AB-rated Loestrin 24 bioequivalent generic at artificially inflated prices. Those prices were substantially greater than the prices that End-Payor Global and Subclass Members would have

paid absent the illegal conduct alleged herein, because: (1) the price of brand Loestrin 24 was artificially inflated by Defendants' illegal conduct, (2) End-Payor Global and Subclass Members were deprived of the opportunity to purchase lower-priced generic versions of Loestrin 24, and/or (3) the price of AB-rated Loestrin 24 generic was artificially inflated by Defendants' illegal conduct.

169. As a consequence, Plaintiffs and End-Payor Global and Subclass Members sustained substantial losses and damage to their business and property in the form of overcharges. The full amount and forms and components of such damages will be calculated after discovery and upon proof at trial.

170. Overcharges at a higher level of distribution generally result in higher prices at every level below.

171. Wholesalers and retailers passed on the inflated prices of Loestrin 24 and AB-rated generic Loestrin 24 to the End-Payor Global and Subclasses.

172. Defendants' anti-competitive conduct enabled them to indirectly charge consumers and third-party payors prices in excess of what Defendants otherwise would have been able to charge absent Defendants' anticompetitive conduct.

173. The prices were inflated as a direct and foreseeable result of Defendants' anticompetitive conduct.

174. The inflated prices the End-Payor Global and Subclasses paid are traceable to, and the causal result of, the overcharges by Defendants.

COUNT I

For Declaratory and Injunctive Relief Under Section 16 of the Clayton Act for Defendants' Violations of Section 1 of the Sherman Act, 15 U.S.C. § 1

(Asserted Against Warner Chilcott and Watson on behalf of the End-Payor Global Class)

175. Plaintiffs repeat and incorporate by reference each preceding and succeeding paragraph as though fully set forth herein.

176. The Watson "Pay-to-Delay" Agreement between Warner Chilcott and Watson involves: (a) a payment from Warner Chilcott to Watson; and (b) an agreement by Watson to delay marketing its generic Loestrin 24 until January 22, 2014 (or earlier in certain circumstances). The payments from Warner Chilcott to Watson under the Agreement were the *quid pro quo* for Watson's agreement to delay marketing its generic version of Loestrin 24 for over four years. Absent the payments, Watson would not have agreed to delay marketing its generic version of Loestrin 24 until January 22, 2014.

177. The purpose and effect of the unlawful Watson "Pay-to-Delay" Agreement between Warner Chilcott and Watson was to allocate 100% of the United States market for oral contraceptives comprising 24 norethindrone acetate/ethinyl estradiol (1mg/20mcg) tablets and four ferrous fumarate tablets to Warner Chilcott; delay the sales of generic Loestrin 24 products for up to over four years; and fix the price at which consumers and other End-Payor Plaintiffs would pay for oral contraceptives comprising 24 norethindrone acetate/ethinyl estradiol (1mg/20mcg) tablets and four ferrous fumarate tablets at the higher, branded price.

178. The Watson "Pay-to-Delay" Agreement covered a substantial percentage of the relevant market sufficient to harm competition.

179. The Watson "Pay-to-Delay" Agreement constitutes a continuing contract, combination and conspiracy in restraint of trade in violation of Section 1 of the Sherman Act, 15 U.S.C. §1. The Watson "Pay-to-Delay" Agreement is a horizontal market allocation and price fixing agreement between actual or potential competitors that is unlawful under the *per se*, "quick look," or rule of reason standard. The purpose and effect of the payments flowing from Warner Chilcott to Watson under the Agreement was to delay generic competition to Loestrin 24, and there is and was no legitimate, non-pretextual, pro-competitive business justification for the payments that outweighs their harmful effect. Even if there were some such conceivable justification, the payments were not necessary to achieve such a purpose.

180. At all relevant times, Warner Chilcott possessed market power in the relevant market. Warner Chilcott possessed the power to control prices in, prevent prices from falling in, and exclude competitors from the relevant market.

181. The goal, purpose and/or effect of the Watson "Pay-to-Delay" Agreement was to prevent and/or delay generic competition to Loestrin 24 and enable Warner Chilcott to continue charging supra-competitive prices for Loestrin 24 without a substantial loss of sales. By means of the Warner Chilcott's payments to Watson, the Defendants shared the supra-competitive profits that their unlawful agreement made possible.

182. Defendants each committed at least one overt act in furtherance of the conspiracy.

183. As a direct and proximate result of Defendants' unlawful restraint of trade, Plaintiffs and End-Payor Global Class Members were harmed as described herein.

184. Plaintiffs and the End-Payor Global Class, pursuant to Fed. R. Civ. P. 57 and 18 U.S.C. § 2201(a), hereby seek a declaratory judgment that Defendants' conduct as described herein violates Section 1 of the Sherman Act.

185. Plaintiffs and the End-Payor Global Class further seek equitable and injunctive relief pursuant to Section 16 of the Clayton Act, 15 U.S.C. § 26, and other applicable law, to correct for the anticompetitive market effects caused by the unlawful conduct of Defendants, and other relief so as to assure that similar anticompetitive conduct does not occur in the future.

COUNT II

For Conspiracy and Combination in Restraint of Trade Under State Law

(Asserted Against Warner Chilcott and Watson on behalf of the End-Payor Subclasses)

186. Plaintiffs repeat and incorporate by reference each preceding and succeeding paragraph as though fully set forth herein.

187. The Watson "Pay-to-Delay" Agreement between Warner Chilcott and Watson involves: (a) payments from Warner Chilcott to Watson; and (b) an agreement by Watson to delay marketing its generic Loestrin 24 until January 22, 2014. The payments from Warner Chilcott to Watson under the Agreement were the *quid pro quo* for Watson's agreement to delay

marketing its generic versions of Loestrin 24 for as long as six years or more. Absent the payments, Watson would not have agreed to delay marketing its generic versions of Loestrin 24 until January 22, 2014.

188. The purpose and effect of the payments flowing from Warner Chilcott to Watson under the agreement was to delay generic competition to Loestrin 24, and there is and was no legitimate, non-pretextual, pro-competitive business justification for the payments that outweighs their harmful effect. Even if there were some such conceivable justification, the payments were not necessary to achieve such a purpose.

189. The purpose and effect of the unlawful Watson "Pay-to-Delay" Agreement between Warner Chilcott and Watson was to allocate 100% of the market for Loestrin 24 and its generic equivalents in the United States to Warner Chilcott; delay the sales of generic Loestrin 24 products for up to over six years; and fix the price at which consumers and other End-Payor Plaintiffs would pay for Loestrin 24 and its generic equivalents at the higher, branded price.

190. The Watson "Pay-to-Delay" Agreement covered a sufficiently substantial percentage of the relevant market to harm competition.

191. As a direct and proximate result of Defendants' unlawful restraint of trade, Plaintiffs and Members of the End-Payor Subclasses paid artificially inflated prices for Loestrin 24 and its generic equivalents as described herein, and were harmed as a result.

192. By engaging in the foregoing conduct, Defendants have violated the following state laws:

a. Defendants have intentionally and wrongfully engaged in a combination and conspiracy in restraint of trade in violation of Fla. Stat. §§ 501. Part II, *et seq.*, with respect to purchases of Loestrin 24 and AB-rated generic equivalents in Florida by End-Payor Florida Subclass Members, and this conduct constitutes a predicate act under the Florida Deceptive Practices Act.

b. Defendants have intentionally and wrongfully engaged in a combination and conspiracy in restraint of trade in violation of Tenn. Code Ann. §§ 47-25-101, *et seq.*, with respect to purchases of Loestrin 24 and AB-rated generic equivalents in Tennessee by End-Payor Tennessee Subclass Members, in that the actions and transactions alleged herein substantially

affected Tennessee, with thousands of end-payors in Tennessee paying substantially higher prices for Loestrin 24 and AB-rated generic equivalents at Tennessee pharmacies.

c. Defendants have intentionally and wrongfully engaged in a combination and conspiracy in restraint of trade in violation of N.C. Gen. Stat. §§ 75-1, *et. seq.*, with respect to purchases of Loestrin 24 and AB-rated generic equivalents in North Carolina by End-Payor North Carolina Subclass Members.

193. Plaintiffs and End-Payor Subclass Members have been injured in their business or property by reason of Defendants' antitrust violations alleged in this Claim. Their injuries consist of: (1) being denied the opportunity to purchase lower-priced generic Loestrin 24, and (2) paying higher prices for branded Loestrin 24 than they otherwise would have paid in the absence of Defendants' conduct. These injuries are of the type the laws of the above States were designed to prevent, and flow from that which makes Defendants' conduct unlawful.

194. Plaintiffs and the End-Payor Subclasses seek all damages permitted by law for their injuries by Defendants' violations of the aforementioned statutes.

COUNT III

For Declaratory and Injunctive Relief Under Section 16 of the Clayton Act for Defendants' Contract, Combination or Conspiracy in Restraint of Trade, Sherman Act Section 1, 15 U.S.C. § 1

(Asserted Against Warner Chilcott and Lupin on behalf of the End-Payor Global Class)

195. Plaintiffs repeat and incorporate by reference each preceding and succeeding paragraph as though fully set forth herein.

196. The Lupin "Pay-to-Delay" Agreement between Warner Chilcott and Lupin involves: (a) payments from Warner Chilcott to Lupin; and (b) an agreement by Lupin to delay marketing its generic Loestrin 24 until July 22, 2014 (or earlier in certain circumstances). The payments from Warner Chilcott to Lupin under the Agreement were the *quid pro quo* for Lupin's agreement to delay marketing its generic version of Loestrin 24 for over four years. Absent the payments, Lupin would not have agreed to delay marketing its generic version of Loestrin 24 until July 22, 2014.

197. The purpose and effect of the unlawful Lupin "Pay-to-Delay" Agreement between Warner Chilcott and Lupin was to allocate 100% of the United States market for oral contraceptives comprising 24 norethindrone acetate/ethinyl estradiol (1mg/20mcg) tablets and four ferrous fumarate tablets to Warner Chilcott; delay the sales of generic Loestrin 24 products for up to over four years; and fix the price at which consumers and other End-Payor Plaintiffs would pay for oral contraceptives comprising 24 norethindrone acetate/ethinyl estradiol (1mg/20mcg) tablets and four ferrous fumarate tablets at the higher, branded price.

198. The Lupin "Pay-to-Delay" Agreement covered a sufficiently substantial percentage of the relevant market to harm competition.

199. The Lupin "Pay-to-Delay" Agreement constitutes a continuing contract, combination and conspiracy in restraint of trade in violation of Section 1 of the Sherman Act, 15 U.S.C. § 1. The Lupin "Pay-to-Delay" Agreement is a horizontal market allocation and price fixing agreement between actual or potential competitors that is unlawful under the *per se*, "quick look," or rule of reason standard. The purpose and effect of the payments flowing from Warner Chilcott to Lupin under the Agreement was to delay generic competition to Loestrin 24, and there is and was no legitimate, non-pretextual, pro-competitive business justification for the payments that outweighs their harmful effect. Even if there were some such conceivable justification, the payments were not necessary to achieve such a purpose.

200. At all relevant times, Warner Chilcott possessed market power in the relevant market. Warner Chilcott possessed the power to control prices in, prevent prices from falling in, and exclude competitors from the relevant market.

201. The goal, purpose and/or effect of the Lupin "Pay-to-Delay" Agreement was to prevent and/or delay generic competition to Loestrin 24 and enable Warner Chilcott to continue charging supra-competitive prices for Loestrin 24 without a substantial loss of sales. By means of the Warner Chilcott's payment to Lupin, the Defendants shared the supra-competitive profits that their unlawful agreement made possible.

202. Defendants each committed at least one overt act in furtherance of the conspiracy.

203. As a direct and proximate result of Defendants' unlawful restraint of trade, Plaintiffs and End-Payor Global Class Members were harmed as described herein.

204. Plaintiffs and the End-Payor Global Class, pursuant to Fed. R. Civ. P. 57 and 18 U.S.C. § 2201(a), hereby seek a declaratory judgment that Defendants' conduct as described herein violates Section 1 of the Sherman Act.

205. Plaintiffs and the Class further seek equitable and injunctive relief pursuant to Section 16 of the Clayton Act, 15 U.S.C. § 26, and other applicable law, to correct for the anticompetitive market effects caused by the unlawful conduct of Defendants, and other relief so as to assure that similar anticompetitive conduct does not occur in the future.

COUNT IV

For Conspiracy and Combination in Restraint of Trade Under State Law

(Asserted Against Warner Chilcott and Lupin on behalf of the End-Payor Subclasses)

206. Plaintiffs repeat and incorporate by reference each preceding and succeeding paragraph as though fully set forth herein.

207. The Lupin "Pay-to-Delay" Agreement between Warner Chilcott and Lupin involves: (a) payments from Warner Chilcott to Lupin; and (b) an agreement by Lupin to delay marketing its generic Loestrin 24 until July 22, 2014. The payments from Warner Chilcott to Lupin under the Agreement were the *quid pro quo* for Lupin's agreement to delay marketing its generic versions of Loestrin 24 for as long as six years or more. Absent the payments, Lupin would not have agreed to delay marketing its generic versions of Loestrin 24 until July 22, 2014.

208. The purpose and effect of the payments flowing from Warner Chilcott to Lupin under the Agreement was to delay generic competition to Loestrin 24, and there is and was no legitimate, non-pretextual, pro-competitive business justification for the payments that outweighs their harmful effect. Even if there were some such conceivable justification, the payment was not necessary to achieve such a purpose.

209. The purpose and effect of the unlawful Lupin "Pay-to-Delay" Agreement between Warner Chilcott and Lupin was to allocate 100% of the market for Loestrin 24 and its generic

equivalents in the United States to Warner Chilcott; delay the sales of generic Loestrin 24 products for up to six years; and fix the price at which consumers and other End-Payor Plaintiffs would pay for Loestrin 24 and its generic equivalents at the higher, branded price.

210. The Lupin "Pay-to-Delay" Agreement covered a sufficiently substantial percentage of the relevant market to harm competition.

211. As a direct and proximate result of Defendants' unlawful restraint of trade, Plaintiffs and other End-Payor Subclass Members paid artificially inflated prices for Loestrin 24 and its generic equivalents as described herein, and were harmed as a result.

212. By engaging in the foregoing conduct, Defendants have violated the following state laws:

a. Defendants have intentionally and wrongfully engaged in a combination and conspiracy in restraint of trade in violation of Fla. Stat. §§ 501. Part II, *et seq.*, with respect to purchases of Loestrin 24 and AB-rated generic equivalents in Florida by End-Payor Florida Subclass Members, and this conduct constitutes a predicate act under the Florida Deceptive Practices Act.

b. Defendants have intentionally and wrongfully engaged in a combination and conspiracy in restraint of trade in violation of Tenn. Code Ann. §§ 47-25-101, *et seq.*, with respect to purchases of Loestrin 24 and AB-rated generic equivalents in Tennessee by End-Payor Tennessee Subclass Members, in that the actions and transactions alleged herein substantially affected Tennessee, with thousands of end-payors in Tennessee paying substantially higher prices for Loestrin 24 and AB-rated generic equivalents at Tennessee pharmacies.

c. Defendants have intentionally and wrongfully engaged in a combination and conspiracy in restraint of trade in violation of N.C. Gen. Stat. §§ 75-1, *et. seq.*, with respect to purchases of Loestrin 24 and AB-rated generic equivalents in North Carolina by End-Payor North Carolina Subclass Members.

213. Plaintiffs and the Subclass Members have been injured in their business or property by reason of Defendants' antitrust violations alleged in this Claim. Their injuries consist of: (1) being denied the opportunity to purchase lower-priced generic Loestrin 24, and (2) paying higher prices for branded Loestrin 24 than they otherwise would have paid in the absence of

Defendants' conduct. These injuries are of the type the laws of the above States were designed to prevent, and flow from that which makes Defendants' conduct unlawful.

214. Plaintiffs and the End-Payor Subclasses seek all damages permitted by law for their injuries by Defendants' violations of the aforementioned statutes.

COUNT V

For Unfair and Deceptive Trade Practices Under State Law

(Asserted Against All Defendants on behalf of the End-Payor Subclasses)

215. Plaintiffs repeat and incorporate by reference each preceding and succeeding paragraph as though fully set forth herein.

216. Defendants engaged in unfair competition and/or unfair, unconscionable, deceptive or fraudulent acts or practices in violation of the state consumer protection statutes listed below. As a direct and proximate result of Defendants' anticompetitive, deceptive, unfair, unconscionable, and fraudulent conduct, Plaintiffs and End-Payor Subclass Members were deprived of the opportunity to purchase a generic version of Loestrin 24 and were forced to pay higher prices. By engaging in the foregoing conduct, Defendants have violated the following state Unfair and Deceptive Trade Practices and Consumer Fraud laws:

a. Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of Fla. Stat. §§ 501.201, *et seq.*, with respect to purchases of Loestrin 24 and AB-rated bioequivalents in Florida by End-Payor Florida Subclass Members.

b. Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of Tenn. Code §§ 47-18-101, *et seq.*, with respect to purchases of Loestrin 24 and AB-rated bioequivalents in Tennessee by End-Payor Tennessee Subclass Members.

c. Defendants have engaged in unfair competition or unfair or deceptive acts practices in violation of N.C. Gen. Stat. §§ 75-1.1 *et. seq.*, with respect to purchases of Loestrin 24 and AB-rated bioequivalents in North Carolina by End-Payor North Carolina Subclass Members.

217. Plaintiffs and the Subclass Members have been injured in their business and property by reason of Defendants' anticompetitive, unfair or deceptive acts alleged in this Claim. Their injury consists of paying higher prices for Loestrin 24 and/or AB-rated bioequivalents than they would have paid in the absence of these violations. This injury is of the type the state consumer protection statutes were designed to prevent and directly results from Defendants' unlawful conduct.

218. Plaintiffs and the End-Payor Subclasses seek all damages permitted by law for their injuries by Defendants' violations of the aforementioned statutes.

COUNT VI

Unjust Enrichment

(Asserted Against All Defendants on behalf of the End-Payor Subclasses)

219. Plaintiffs repeat and incorporate by reference each preceding and succeeding paragraph as though fully set forth herein.

220. Defendants have benefited from splitting the monopoly profits on Warner Chilcott's Loestrin 24 sales that result from the unlawful and inequitable acts alleged in this Complaint.

221. Defendants' financial benefits resulting from their unlawful and inequitable conduct are traceable to overpayments for Loestrin 24 and its generic equivalents by Plaintiffs and End-Payor Subclass Members.

222. Plaintiffs and the End-Payor Subclasses have conferred upon Defendants an economic benefit, in the nature of profits resulting from unlawful overcharges and monopoly profits, to the economic detriment of Plaintiffs and the End-Payor Subclasses.

223. It would be futile for Plaintiffs and the End-Payor Subclasses to seek a remedy from any party with whom they had privity of contract. Defendants have paid no consideration to anyone for any benefits received indirectly from Plaintiffs and the End-Payor Subclasses.

224. It would be futile for Plaintiffs and the End-Payor Subclasses to seek to exhaust any remedy against the immediate intermediary in the chain of distribution from which it

indirectly purchased Loestrin 24 or its generic equivalents, as they are not liable and would not compensate Plaintiffs for unlawful conduct caused by Defendants.

225. The economic benefit of overcharges and unlawful monopoly profits derived by Defendants through charging supra-competitive and artificially inflated prices for Loestrin 24 and/or its generic equivalents is a direct and proximate result of Defendants' unlawful practices.

226. The financial benefits derived by Defendants rightfully belongs to Plaintiffs and the End-Payor Subclasses, as Plaintiffs and the End-Payor Subclasses paid supra-competitive and monopolistic prices during the Class Period, inuring to the benefit of Defendants.

227. It would be inequitable under the laws of all states and jurisdictions within the United States for the Defendants to be permitted to retain any of the overcharges for Loestrin 24 and/or AB-rated bioequivalents derived from Defendants' unfair and unconscionable methods, acts and trade practices alleged in this Complaint.

228. Defendants should be compelled to disgorge in a common fund for the benefit of Plaintiffs and the End-Payor Subclasses all unlawful or inequitable proceeds received by them.

229. A constructive trust should be imposed upon all unlawful or inequitable sums received by Defendants traceable to Plaintiffs and the End-Payor Subclasses.

230. Plaintiffs and the End-Payor Subclasses have no adequate remedy at law.

DEMAND FOR JUDGMENT

WHEREFORE, Plaintiffs, on behalf of themselves and the End-Payor Global Class and the End-Payor Subclasses, demand judgment for the following relief:

A. Determine that this action may be maintained as a class action pursuant to Fed. R. Civ. P. 23(a) and (b)(3), and direct that reasonable notice of this action, as provided by Fed. R. Civ. P. 23(c)(2), be given to the End-Payor Global and Subclasses and declare the Plaintiffs representatives of the End-Payor Global and Subclasses;

B. Declare the conduct alleged herein is in violation of Section 1 of the Sherman Act, of the other statutes set forth above, and of the common law of unjust enrichment under the laws of the States of Tennessee, North Carolina and Florida;

C. Enjoin Defendants from continuing the illegal activities alleged herein;

D. Enter joint and several judgments against Defendants in favor of Plaintiffs and the End-Payor Global and Subclasses;

E. Grant Plaintiffs and the End-Payor Global and Subclasses equitable relief in the nature of disgorgement, restitution, and the creation of a construction trust to remedy Defendants' unjust enrichment;

F. Award Plaintiffs and the End-Payor Global and Subclasses damages and, where applicable, treble, multiple, punitive, and/or other damages, in an amount to be determined at trial, including interest;

G. Award Plaintiffs and the End-Payor Global and Subclasses their costs of suit, including reasonable attorneys' fees as provided by law; and

H. Grant such other further relief as is necessary to correct for the anticompetitive market effects caused by the unlawful conduct of Defendants, and as the Court deems just.

JURY DEMAND

Pursuant to Fed. Civ. P. 38, Plaintiffs on behalf of themselves and the proposed End-Payor Global and Subclasses demand trial by jury on all issues so triable.

Dated: October 16, 2013

Donald Migliori
MOTLEY RICE
321 South Main St., 2nd Floor
Providence, RI 02903
Telephone: (401) 457-7700
Facsimile: (401) 457-7708

-and-

William J. Doyle, II
James R. Hail
Chris W. Cantrell
(Admission *pro hac vice* to be sought)
DOYLE LOWTHER LLP

10200 Willow Creek Road, Suite 150
San Diego, California 92131
Telephone: (858) 935-9960
Facsimile: (858) 939-1939
Counsel for Plaintiffs